

THE CANCER PROJECT

5100 Wisconsin Avenue, NW, Suite 400
Washington, DC 20016
Telephone: (202) 527-7380
Facsimile: (202) 527-7480
Attorneys for Plaintiffs

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JOHN O'DONNELL, RUTHANN
HILLAND, and MICHELE DE SCISCIOLO
for themselves and a class of consumers
similarly situated,

Plaintiffs,

v.

KRAFT FOODS INC., manufacturer of the
Oscar Mayer brand; SARA LEE
CORPORATION, manufacturer of the Ball
Park brand; CONAGRA FOODS, INC.,
manufacturer of the Hebrew National brand;
NATHAN'S FAMOUS, INC., manufacturer
of the Nathan's Famous brand; and
MARATHON ENTERPRISES, INC.,
manufacturer of the Sabrett brand,

Defendants.

CIVIL ACTION NO. 09-04448-JLL-CCC

**DECLARATION OF DANIEL
KINBURN IN OPPOSITION TO
DEFENDANTS' JOINT MOTION TO
DISMISS THE COMPLAINT**

I, DANIEL KINBURN, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am general counsel for The Cancer Project, attorneys for all Plaintiffs in this case.
2. On October 9, 2008, The Cancer Project submitted a *Petition to the United States Department of Agriculture for Enforcement and Rulemaking* with the United States Department of Agriculture ("USDA"). A true and correct copy of that petition, minus appendices, is attached hereto as Exhibit A.

3. I personally received a letter, dated December 23, 2008, from Edward T. Schafer, Secretary of USDA, in response to the petition filed by The Cancer Project on October 9, 2008. A true and correct copy of that letter is attached hereto as Exhibit B.

4. On June 16, 2009, The Cancer Project submitted an *Amended Petition to the United States Department of Agriculture for Enforcement and Rulemaking* with USDA. A true and correct copy of that petition, minus appendices, is attached hereto as Exhibit C.

5. I personally received a letter, dated October 7, 2009, from Philip S. Derfler, Assistant Administrator, Office of Policy and Program Development, USDA, in response to the petition filed by The Cancer Project on June 16, 2009. A true and correct copy of that letter is attached hereto as Exhibit D.

6. I declare under penalty of perjury that the foregoing is true and correct.

Executed on November 9, 2009

By: 

Daniel Kinburn

Exhibit A



5100 WISCONSIN AVE., N.W., SUITE 400
WASHINGTON, DC 20016
PHONE: 202-244-5038
FAX: 202-686-2216
WWW.CANCERPROJECT.ORG

Advancing cancer prevention and survival through nutrition education and research.

**PETITION TO THE UNITED STATES DEPARTMENT OF AGRICULTURE
FOR ENFORCEMENT AND RULEMAKING**

Submitted to:
Secretary of Agriculture, Ed Schafer
United States Department of Agriculture
1400 Independence Ave., SW
Washington, DC 20250

On: October 9, 2008

Submitted by:
The Cancer Project
5100 Wisconsin Ave., NW
Suite 400
Washington, DC 20016
(202) 686-2210

I. INTRODUCTION

The U.S. Department of Agriculture's ("USDA") Food and Nutrition Service ("FNS") is charged with providing nutritious foods to the nation's children and needy adults while at the same time strengthening American agriculture. In this capacity, the USDA purchases commodities to remove surpluses from the marketplace and delivers them through food distribution programs to state agencies. The state agencies then provide the commodities to schools and other outlets.

Petitioner, The Cancer Project ("TCP"), is alarmed by the USDA's failure to adequately protect the nation's children by unnecessarily exposing children to significantly increased risk of cancer. Specifically, the USDA permits commodity meats and poultry to be processed in such a way as to increase their carcinogenic potential and then distributed to children through the National School Lunch program, despite the substantial body of scientific evidence attributing the consumption of processed meat to significantly increasing the risk of various forms of cancer. In doing so, the USDA fails to implement one of the primary goals of the National School Lunch Act, 42 U.S.C. § 1751, which is to safeguard and improve children's health. Accordingly, TCP submits this petition, pursuant to the Right to Petition Government Clause contained in the First Amendment

of the United States Constitution,¹ the Administrative Procedure Act,² and the USDA's implementing regulations,³ requesting that the Secretary of the USDA take the following actions necessary to comply with the express intent of the National School Lunch Act and end federal support and encouragement of unhealthy foods in school lunches for children.

II. ACTION REQUESTED

The Cancer Project petitions the Secretary of the United States Department of Agriculture to:

- (1) Institute an examination or investigation into the significant dangers of processed meats⁴ in light of the increasing and plentiful body of accepted scientific evidence concluding that the ingestion of processed meat products causes an increased risk of cancer, especially colorectal cancer.
- (2) Determine whether the USDA may continue to make available unhealthful processed meats for purchase, subsidy, and reimbursement, and comply with the National School Lunch Act, 42 U.S.C. § 1751, which mandates:

[A]s a measure of national security, to safeguard the health and well-being of the Nation's children and to encourage the domestic consumption of nutritious agricultural commodities and other food, by assisting the States, through grants-in-aid and other means, in providing an adequate supply of foods and other facilities for the establishment, maintenance, operation, and expansion of nonprofit school lunch programs.

- (3) Discontinue the inclusion of processed meats and poultry on the list of commodities available for purchase from the USDA under the Child Nutrition Commodity Programs including the National School Lunch Program, in light of the findings sought in (1) and (2).
- (4) Discontinue reimbursement, under the Child Nutrition Commodity Programs including the National School Lunch Program, to schools for lunches that include processed meats.

¹ U.S. Const. amend I.

² 5 U.S.C. § 553(e).

³ 7 C.F.R. § 1.28

⁴ "Processed meat" refers to meat preserved by smoking, curing or salting, or addition of chemical preservatives such as nitrites and nitrates, including that contained in processed foods. See World Cancer Research Fund ("WCRF") and American Institute for Cancer Research ("AICR") (2007). *Second Report on Food, Nutrition, Physical Activity and the Prevention of Cancer: a Global Perspective* ("WCRF Second Report") at xix.

- (5) Encourage schools that offer processed meats to offer alternatives to processed meats in their meal plans and at school-hosted functions.
- (6) Promulgate regulations determining processed meat and poultry products to be unhealthful and a leading cause of colorectal cancer and thus unavailable for funding, purchasing, or reimbursement through the Child Nutrition Commodity Programs including the National School Lunch Program.
- (7) Enforce 7 C.F.R. § 210.10 by requiring the FNS nutrition education program to provide information and educational material on the deleterious effects of processed meats on human health to state agencies, schools, parents, and students.
- (8) Discontinue the announcement for and the receipt of bids from suppliers selling to the USDA, for redistribution through the Child Nutrition Commodity Programs including the National School Lunch Program, processed meat products, including ham, luncheon meat, pork sausage crumbles, pork sausage links, pork sausage patties, pork sloppy joes, and any other processed meat or poultry found to increase the risk of cancer.

III. PARTIES

Petitioner, The Cancer Project, is a national health advocacy nonprofit located at 5100 Wisconsin Ave., NW, Washington, D.C., 20016. TCP is a collaboration of physicians, researchers, and nutritionists joining together to educate the public about the benefits of a healthy diet for cancer prevention and survival. TCP offers free nutrition classes throughout the country, conducts research, and advocates for healthier federal food policies.

IV. ARGUMENT

THE USDA FAILS TO COMPLY WITH THE NATIONAL SCHOOL LUNCH ACT BY PERMITTING COMMODITY MEAT TO BE PROCESSED AND THEN DISTRIBUTED, SUBSIDIZED, AND REIMBURSED THROUGH THE NATIONAL SCHOOL LUNCH PROGRAM

Congress has repeatedly given the USDA the authority to protect both the health and welfare of the nation's children and to protect and cultivate the nation's agricultural sector. In passing the National School Lunch Act, 42 U.S.C.A. § 1751, *et seq.*, Congress expressly mandated the dual goals of supporting "the health and well-being of the Nation's children" and "encourag[ing] the domestic consumption of nutritious

agricultural commodities.” However, the USDA compromises the health of the nation’s children by ignoring convincing and accepted scientific evidence on the deleterious effects of consumption of processed meat and poultry. Contravening its mandate, the USDA facilitates, permits, and funds the purchase of processed meat and poultry for children in school, thus increasing their risk of cancer.

Processed meat products, including ham, bacon, pastrami, salami, bologna, liverwurst, bratwurst, sausages, frankfurters, hot dogs, luncheon meats, and, depending on the processing, hamburgers and minced meats,⁵ represent a broad category of meat products that are often prepared and/or preserved by curing, smoking, salting, or adding chemical preservatives, such as nitrites and nitrates. A review of 58 scientific studies concluded that consuming processed meat is strongly associated with the increased risk of colorectal cancer,⁶ the fourth most common cancer in men and women.⁷

Cancer risk is strongly influenced by environmental exposures; the intestinal tract is in constant contact with foods, food additives, and the products of digestion. This means that individuals who consume processed meats are at a significantly increased risk of developing colorectal cancer, compared with those who avoid consuming processed meats. Moreover, the risk increases with increased consumption. According to the World Cancer Research Fund and American Institute for Cancer Research, risk increases on average by 21 percent for every 50 grams of processed meat consumed daily. A 50-gram serving is approximately the size of a typical hot dog. The review also cites evidence that consuming processed meats may also contribute to cancers of the esophagus, lung, stomach, and prostate.⁸

Thus, in order to protect the health and well-being of the nation’s children, the USDA must eliminate the availability of processed meats through the Child Nutrition Commodity Programs including the National School Lunch Program. By acting on the requests made by TCP, the USDA will be in compliance with the National School Lunch Act, 42 U.S.C.A. § 1751, *et seq.* And in doing so, the USDA will meet its responsibilities to the nation’s children. Moreover, this can be achieved while allowing processed meats to be sold at prices set by the marketplace, not by the federal government.

In determining the nutritious quality of a school lunch, the USDA considers many factors. For example, school lunches must meet the applicable recommendations of the Dietary Guidelines for Americans, which recommend that no more than 30 percent of an individual’s calories come from fat and less than 10 percent from saturated fat.

⁵ See WCRF and AICR (2007). *WCRF Second Report* at 117; and Ward, M.H. et al. (2007). *Processed meat intake, CYP2A6 activity and risk of colorectal adenoma*. *CARCINOGENESIS* 28(6): 1210-1216, 1210.

⁶ In 2007, the World Cancer Research Fund and American Institute for Cancer Research released a report, *Food, Nutrition, Physical Activity and the Prevention of Cancer: a Global Perspective* that concluded that “Processed meat is a convincing cause of colorectal cancer.” *WCRF Second Report* at 123.

⁷ The National Cancer Institute estimates predict that, in 2008, 108,070 individuals will develop colon cancer, 40,740 will develop rectal cancer, and 49,960 will die from these conditions. (NCI 2008).

⁸ *WCRF Second Report* at 128;

Regulations also establish a standard for school lunches to provide one-third of the Recommended Dietary Allowances of protein, vitamin A, vitamin C, iron, calcium, and calories. However, the USDA fails to look at other attributes of food in determining whether it is healthful for inclusion in the school lunch menu. As noted above, the overall healthfulness of food goes beyond the caloric content, fat, and cholesterol. Both the food itself and the cooking process must be examined for overall wholesome qualities, including the risk of cancer and exposure to any other risk of disease or ailment through the National School Lunch Program and Commodity Programs.

V. SCIENTIFIC EVIDENCE SUPPORTING TCP'S PETITION

The link between eating processed meats and cancer has been long studied.⁹ In order to establish consensus on the state of evidence supporting links between specific types of food and cancer risk, the World Cancer Research Fund¹⁰ and the American Institute for Cancer Research¹¹ created a panel that, over a five-year period, studied evidence regarding the extent to which cancer can be prevented through healthy patterns of eating and physical activity and created a comprehensive report based on its findings. Previously, the groups had worked together to create and publish *Food, Nutrition and the Prevention of Cancer: a Global Perspective* (1997), which quickly became the standard in the field and helped raise awareness about the importance of research on this issue.¹²

The panel's report reviewed all relevant research using the most scientifically valid methodology, provided a comprehensive assessment of the state of evidence linking foods to cancer risk, and provided a set of recommendations on food, nutrition, and physical activity to reduce the risk of cancer.¹³ The panel consisted of world-renowned scientists, including world leaders in research of the epidemiology and biology of cancer, nutrition, and public health. To maximize objectivity and transparency of the project, it was separated into three distinct processes: 1) the collection, 2) the analysis, and 3) the recommendations. First, a task force developed a methodology for reviewing the voluminous amounts of scientific literature. Second, research teams collected and reviewed the material based on the developed methodology. And finally, the expert panel assessed and judged the evidence and agreed on recommendations. A copy of the report is attached and incorporated herein by reference.

Although the cancer process begins with damage to genes, only a small percentage of cancer is inherited, leaving environmental factors, including food and nutrition, as the

⁹ See *WCRF Second Report* at 116.

¹⁰ The WCRF global network raises awareness that cancer is largely preventable, funds innovative scientific research and stimulates world wide public health initiatives for the control and prevention of cancer. http://www.wcrf.org/home/about_wcrf_intl.lasso (last accessed on May 28, 2008).

¹¹ American Institute for Cancer Research fosters research on diet and cancer prevention, interprets the evidence, and educates the public about the results.

¹² *WCRF Second Report* at xiv.

¹³ *Id.*

most important and modifiable.¹⁴ It has long been estimated that anywhere from 35 to 60 percent of cancer is attributable to diet.¹⁵ “To the extent that environmental factors such as food, nutrition, and physical activity influence the risk of cancer, it is a preventable disease.”¹⁶ Accordingly, the report includes among its recommendations that processed meats be eliminated from people’s diets.¹⁷

a. Processed Meats and the Risk of Cancer

Processed meats and poultry products contain a variety of potentially carcinogenic chemicals, especially when smoked, cured, preserved, grilled, or cooked at high temperatures. These may include nitrates, nitrites, N-nitroso compounds (“NOCs”) such as N-nitrosodimethylamine (“NDMA”), heme iron, heterocyclic amines (“HCAs”), such as 2-amino-1-methyl-6-phenylimidazo[4,5-b]pyridine (“PhIP”) and 2-amino-3,8-dimethylimidazo[4,5]quinoxaline (“MeIQx”), and polycyclic aromatic hydrocarbons (“PAHs”), such as benzo[α]pyrene (“BAP”).¹⁸ The associated cancer risks from these chemical components through the consumption of processed meat products have been described for decades. N-nitrosamines and NOCs were identified as carcinogenic substances over 50 years ago.¹⁹

Nitrites used in meats as a preservative, as well as a coloring and flavoring agent, can combine with amino acid degradation products during the curing process or during digestion to produce N-nitroso compounds (nitrosamines or nitrosamides). Nitrates, used as preservatives, are converted to nitrites. In addition, processed meats cooked at high temperatures may contain chemical carcinogens, including HCAs and PAHs. Moreover, heme iron, plentiful in red and processed meats, promotes the production of N-nitroso compounds, and its iron content leads to free radical production.

Substantial evidence from cohort and case-control studies indicates that processed meat is a convincing cause of colorectal cancer. Meta-analyses find a 21 percent increased risk per 50-gram serving per day.²⁰

b. Chemicals that Increase the Risk of Cancer

i. NOCs

¹⁴ *Id.*

¹⁵ National Cancer Institute. *Cancer Rates and Risks*. Washington, DC:1985, Doll R, Peto R. *The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the United States today*. J Natl Cancer Inst. 1981; 66:1191-308.

¹⁶ *WCRF Second Report* at xiv.

¹⁷ *Id.* at 382.

¹⁸ Jakszyn, P. et al. (2004). *Development of a Food Database of Nitrosamines, Heterocyclic Amines, and Polycyclic Aromatic Hydrocarbons*. J. NUTR. 134: 2011-2014, 2011.

¹⁹ See Bartsch, H. and Montesano, R. (1984). *Relevance of nitrosamines to human cancer*. CARCINOGENESIS 5(11): 1381-1393, 1381.

²⁰ *WCRF Second Report* at 123.

A body of scientific literature concludes that NOCs exhibit mutagenic and carcinogenic activity and are associated with an increased risk of cancer of the esophagus, oral cavity, pharynx, larynx, lung, and colorectum.²¹ NOCs are formed as a result of the nitrosation of amines, amides, and amino acids by nitrites and nitrates, which are commonly used as food preservatives in processed meat products.²² Consumption of processed meat, especially processed red meat, has a consistent dose response with the endogenous formation of NOCs resulting in increased amounts of these compounds in the gastrointestinal tract.²³ Thus, due to the endogenous and exogenous exposure from NOCs through the consumption of processed meat products, consumers of these products have an increased risk for gastrointestinal cancers, such as colorectal cancer.²⁴ Additionally, NOC metabolites (metabolically activated NOCs) may contribute to an increased risk of leukemia as well as colon, stomach, esophagus, and brain cancer by inducing the formation of DNA-adducts and miscoding of non-complementary bases during polyribonucleotide and polydeoxyribonucleotide synthesis.²⁵ It is important to note that no safe threshold dose, at which tumor formation would not be expected to occur, has been determined for NOCs. Moreover, NOCs that are carcinogenic in animals are commonly considered human carcinogens for regulatory purposes when establishing safety levels.²⁶

One of the most studied NOCs, NDMA, a nitrosamine present in processed meat products, was listed as a human carcinogen by the State of California in 1987.²⁷ Similarly, the International Agency for Research on Cancer ("IARC"), which is part of the World Health Organization, identified NDMA as a probable and possible human

²¹ See Cross A.J. et al. (2007).

²² Larsson, S.C., Orsini, N. and Wolk, A. (2006). *Processed Meat Consumption and Stomach Cancer Risk: A Meta-Analysis*. J. NATL. CANC. INST. 98(15): 1078-1087, 1085.

²³ See Lunn, J., Pollock, J. and Bingham, S. (2004). *The effect of increased red and processed meat on endogenous formation of N-nitroso compounds and DNA strand breaks in ileostomists*. CANCER EPIDEMIOL. BIOMARKERS PREV. 13: A 95-1852.

²⁴ Mirvish, S.S. et al. (2002) at 35268 and See Jakszyn, P. et al. (2006). *Endogenous versus exogenous exposure to N-nitroso compounds and gastric cancer risk in the European Prospective Investigation into Cancer and Nutrition (EPIC-EURGAST) study*. CARCINOGENESIS 27(7): 1497-1501, 1499; Risch, H.A. (2003). *Etiology of Pancreatic Cancer, With a Hypothesis Concerning the Role of N-Nitroso Compounds and Excess Gastric Acidity*. J. NATL. CANC. INST. 95(13): 948-960, 950.

²⁵ Mirvish, S.S. et al. (2002) at 35268; Bartsch, H. and Montesano, R. (1984). *Relevance of nitrosamines to human cancer*. CARCINOGENESIS 5(11): 1381-1393, 1384-1385; also see Bingham, S.A. (2000). *Diet and colorectal cancer prevention*. BIOCHEM. SOCIETY TRANSACTIONS 28(2): 12-16.

²⁶ European Commission, Scientific Committee for Food (1995). *Report of the Scientific Committee for Food*, 38th Series: 1-54, 20 and See Bingham, S.A. et al. (2002). *Effect of white versus red meat on endogenous N-nitrosation in the human colon and further evidence of a dose response*. J. NUTR., 132, 3522S-3525S; Cross, A.J. et al. (2003). *Haem, not protein or inorganic iron, is responsible for endogenous intestinal N-nitrosation arising from red meat*. CANCER RES., 63, 2358-2360.

²⁷ See Environmental Protection Agency Office of Environmental Health Hazard Assessment ("OEHHHA") (2008). *Chemicals Known to the State to Cause Cancer or Reproductive Toxicity*. http://www.oehha.ca.gov/prop65/prop65_list/files/singlelist032108.xls (last accessed March 21, 2008).

carcinogen.²⁸ The U.S. Department of Health and Human Services (“DHHS”) identified NDMA as a substance reasonably anticipated to cause cancer.²⁹

ii. HEME

Heme, a red organic pigment, is the iron porphyrin component of hemoproteins, such as hemoglobin and myoglobin.³⁰ Dietary heme forms a highly cytotoxic metabolite that damages the colonic mucosa, resulting in the increased risk of gastric and colon cancer.³¹ Due to the contribution of heme to NOC formation, the consumption of nitrate and nitrite-rich processed meat products leads to an increased risk for gastrointestinal cancers, such as colorectal cancer. Heme iron, as opposed to inorganic iron, is considered to be a principal determinant of endogenous gastrointestinal N-nitrosation by acting as a nitrosating agent, and, for reasons similar to those applied to NOCs, cannot have a determined safe threshold level.³²

iii. HCAs

HCAs have been considered major contributors to mutagenicity of cooked meat products. Therefore, consuming these products poses a public health risk. Through metabolic pathways such as cytochrome-mediated (e.g., CYP1 and CYP2) N-hydroxylation and O-esterification by phase II enzymes, HCA compounds create genotoxic metabolites that are known mutagens and carcinogens.³³ HCAs form inside and on the surface of meats from creatine or creatinine, amino acids, and sugars as a result of exposure to high temperatures through cooking processes, including barbecuing, frying, roasting, and grilling.³⁴

HCAs detected in cooked processed meat products that are suspected of increasing cancer risk include 2-amino-3-methylimidazo[4,5-f]quinoline.³⁵ The HCAs 2-amino-3,4,8-trimethylimidazo[4,5]quinoxaline, MeIQx, and PhIP are specifically linked to an increased risk for colorectal cancer.³⁶ The State of California has identified PhIP and

²⁸ See IARC (2007). *Agents Reviewed by the IARC Monographs, Vols. 1-98*, 4.

<http://monographs.iarc.fr/ENG/Classification/Listagentsalphorder.pdf> (last accessed March 21, 2008).

²⁹ See U.S. DHHS, Public Health Service, National Toxicology Program (2005). *Report on Carcinogens, Eleventh Edition*. <http://ntp.niehs.nih.gov/index.cfm?objectid=32BA9724-F1F6-975E-7FCE50709CB4C932> (last accessed March 21, 2008).

³⁰ Balder, H.F. et al. (2006). *Heme and Chlorophyll Intake and Risk of Colorectal Cancer in the Netherlands Cohort Study*. *CANCER EPIDEMIOLOGY AND BIOMARKERS* 15(4): 717-725, 717.

³¹ See Balder, H.F. et al. (2006) at 717; Lunn, J.C. et al. (2004) at 689.

³² See Ward, M.H. et al. (2007) at 1215; Cross, A.J. et al. (2007); Jakszyn, P. et al. (2006) at 1497.

³³ See Gooderham, N.J. et al. (2001-a). *Food-Derived Heterocyclic Amine Mutagens: Variable Metabolism and Significance to Humans*. *DRUG METABOLISM AND DISPOSITION* 29(4): 529-534, 529.

³⁴ Kikugawa, K. (2004). *Prevention of mutagen formation in heated meats and model systems*. *MUTAGENESIS* 19(6): 431-439, 431.

³⁵ See IARC. *Some Naturally Occurring Substances: Food Items and Constituents, Heterocyclic Aromatic Amines and Mycotoxins*, Vol. 56 at 11.

¹¹ <http://monographs.iarc.fr/ENG/Monographs/vol56/volume56.pdf> (last accessed March 20, 2008).

³⁶ See Sinha, R. et al. (2005). *Meat, Meat Cooking Methods and Preservation, and Risk for Colorectal Adenoma*. *CANCER RES.* 65(17): 8034-8042.

MeIQx as known human carcinogens since 1994,³⁷ and the IARC labeled them as possible human carcinogens in 1993.³⁸ Because there are no known safe levels of exposure, PhIP, MeIQx, and any other likely genotoxic compounds should be avoided as much as possible.³⁹

iv. PAHs

Studied for decades, PAHs have also been found to contribute to mutagenic and carcinogenic activity. Processed meat products contain precursors to PAHs, creating PAHs when animal fat drips onto a heated surface and burns.⁴⁰ Processed meat products are thereby of concern due to the routine use of high temperature cooking methods to prepare such foods.⁴¹ Through a process of metabolic activation by cytochrome P450 enzymes and/or peroxidases, PAHs become reactive intermediates with carcinogenic potential.⁴² PAH exposure results in genotoxic markers such as DNA adducts, chromosome aberrations, sister chromatid exchanges, *ras* oncogene over expression, and impacts on cellular pathways.⁴³ PAHs generally exist in complex mixtures, making it difficult to pinpoint the relative contribution of any individual PAH to carcinogenic effects.

However, one of the most prevalent and readily identifiable carcinogenic PAHs is BAP.⁴⁴ Since the 1930s, BAP has been studied for its carcinogenic effect.⁴⁵ BAP was listed as a known carcinogen by the State of California in 1987 and was upgraded to this status by the IARC in 2007.⁴⁶ The DHHS has identified BAP and PAHs as substances reasonably

³⁷ OEHHA (2008). *Chemicals Known to the State to Cause Cancer or Reproductive Toxicity*. http://www.oehha.ca.gov/prop65/prop65_list/files/singlelist032108.xls (last accessed March 21, 2008).

³⁸ IARC (2007). *Agents Reviewed by the IARC Monographs, Vols. 1-98*, 4. <http://monographs.iarc.fr/ENG/Classification/Listagentsalphorder.pdf> (last accessed March 21, 2008).

³⁹ Food Standards Australia New Zealand (2005). *Scientific Assessment of the Public Health and Safety of Poultry Meat in Australia*. 1-228, 172;

http://www.foodstandards.gov.au/_srcfiles/P282_Poultry%20_%20DAR%20Attach3.doc (last accessed March 24, 2008). Gooderham, N.J. et al. (1996). *Heterocyclic amines: evaluation of their role in diet associated with human cancer*. BR. J. CLIN. PHARMACOL. 42: 91-98, 91.

⁴⁰ Sinha, R. et al. (2005). *Dietary Benzo[a]Pyrene Intake and Risk of Colorectal Adenoma*. CANCER EPIDEMIOL. BIOMARKERS PREV. 14(8): 2030-2034, 2030.

⁴¹ See IARC: Polycyclic Aromatic Hydrocarbons, § 5.4, August 2006.

<http://monographs.iarc.fr/ENG/Meetings/92-pahs.pdf> (last accessed March 20, 2008).

⁴² Melendez-Colon, V.J., Luch, A., Seidel, A. and Barid, W.M. (1999). *Cancer initiation by polycyclic aromatic hydrocarbons results from formation of stable DNA adducts rather than apurinic sites*. CARCINOGENESIS 20(10): 1885-1891, 1885.

⁴³ Ding et al. (2006). *Effects of Polycyclic Aromatic Hydrocarbons (PAHs) on Vascular Endothelial Growth Factor Induction through Phosphatidylinositol 3-Kinase/AP-1-dependent HIF-1 α -Independent Pathway*. J. BIOL. CHEM. 281(14): 9093-9100, 9099.

⁴⁴ See IARC (2007). *Overall Evaluations of Carcinogenicity to Humans*.

<http://monographs.iarc.fr/ENG/Classification/crthgr01.php> (last accessed March 20, 2008).

⁴⁵ Rubin, H. (2001). *Synergistic mechanisms in carcinogenesis by polycyclic aromatic hydrocarbons and by tobacco smoke: a biohistorical perspective with updates*. CARCINOGENESIS 22(12): 1903-1930, 1903.

⁴⁶ IARC (2007). *Agents Reviewed by the IARC Monographs, Vols. 1-98*, 4. <http://monographs.iarc.fr/ENG/Classification/Listagentsalphorder.pdf> (last accessed March 21, 2008);

anticipated to cause cancer.⁴⁷ Because there is no known safe level of exposure for BAP or other genotoxic PAHs, they should be avoided as much as possible.⁴⁸

VI. CONCLUSION

In light of the evidence presented in this petition, and in order for the agency to comply with its own statutory and regulatory requirements, TCP requests that the USDA enact the suggested rulemaking and amendments to particular rules to bring the USDA's programs into compliance with the National School Lunch Act. As required by 7 C.F.R. § 1.28, the USDA is required to give this petition prompt consideration. Therefore, TCP requests a substantive response to this petition within one hundred eighty (180) calendar days.⁴⁹

Respectfully submitted,



Neal D. Barnard, M.D.
President
The Cancer Project
5100 Wisconsin Ave., NW, Suite 400
Washington, D.C. 20016
(202) 686-2210

OEHHA (2008). *Chemicals Known to the State to Cause Cancer or Reproductive Toxicity*. http://www.oehha.ca.gov/prop65/prop65_list/files/singlelist032108.xls (last accessed March 21, 2008).

⁴⁷ U.S. DHHS, Public Health Service, National Toxicology Program (2005). *Report on Carcinogens, Eleventh Edition*. <http://ntp.niehs.nih.gov/index.cfm?objectid=32BA9724-F1F6-975E-7FCE50709CB4C932> (last accessed March 21, 2008).

⁴⁸ *Id.* at 169.

⁴⁹ See 42 U.S.C. § 7604(a) requiring notice of 180 days prior to commencing an action for unreasonable delay.

A handwritten signature in black ink, appearing to read "Dan Kinburn", with a long horizontal flourish extending to the right.

Daniel Kinburn
General Counsel
The Cancer Project
5100 Wisconsin Ave., N.W., Suite 400
Washington, D.C. 20016
(202) 686-2210

Exhibit B



United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

DEC 23 2008

Mr. Daniel Kinburn
General Counsel
The Cancer Project
5100 Wisconsin Avenue NW., Suite 400
Washington, D.C. 20016

Dear Mr. Kinburn:

Thank you for your October 9, 2008, petition regarding processed meats. Your petition, submitted in accordance with Departmental requirements at 7 CFR 1.28, includes a request to ban processed meats from the National School Lunch Program (NSLP).

The Department of Agriculture (USDA) sets minimum nutritional standards and establishes the NSLP meal patterns to comply with the *Dietary Guidelines for Americans*. The actual foods offered in the NSLP are determined by the local school food authorities and reflect not only the meal pattern requirements, but also cost and taste preferences of the local student body. To date, we are not aware of any evidence that would cause us to ban processed meat products in the school lunch program. USDA will not promulgate a proposed rulemaking to ban such products until the appropriate expert organizations and governmental agencies have determined that serving these meat items is unsafe.

Once again, thank you for the Program interest your petition clearly conveys, but as the concerns raised in your submission have not been endorsed by the appropriate regulatory authorities, the Department would have no basis to act.

Sincerely,

A handwritten signature in dark ink, appearing to read "E. Schafer", is written over a horizontal line.

Edward T. Schafer
Secretary

Exhibit C



5100 WISCONSIN AVE., N.W., SUITE 400
WASHINGTON, DC 20016
PHONE: 202-244-5038
FAX: 202-686-2216
WWW.CANCERPROJECT.ORG

Advancing cancer prevention and survival through nutrition education and research.

**AMENDED PETITION TO THE UNITED STATES DEPARTMENT OF
AGRICULTURE FOR ENFORCEMENT AND RULEMAKING**

Submitted to:

Secretary of Agriculture, Tom Vilsack
United States Department of Agriculture
1400 Independence Ave., SW
Washington, DC 20250

On: June 16, 2009

Submitted by:

The Cancer Project
5100 Wisconsin Ave., NW
Suite 400
Washington, DC 20016
(202) 686-2210

I. INTRODUCTION

The U.S. Department of Agriculture's ("USDA") Food and Nutrition Service ("FNS") is charged with providing nutritious foods to the nation's children and needy adults while at the same time strengthening American agriculture. In this capacity, the USDA purchases commodities to remove surpluses from the marketplace and delivers them through food distribution programs to state agencies. The state agencies then provide the commodities to schools and other outlets.

Last year, The Cancer Project ("TCP") petitioned the USDA to address its failure to adequately protect the nation's children by unnecessarily exposing children to significantly increased risk of cancer. The petition requested that USDA exercise its authority to prohibit the distribution of processed commodity meats and poultry through the National School Lunch program due to the increased risk of cancer that results from children's consumption of processed meat and poultry. The USDA rejected the petition, asserting that it was "not aware of any evidence" that would cause it to take the requested action. The USDA also said that it would not take the requested action until "the appropriate expert organizations and government agencies have determined that serving these meat items is unsafe." A copy of the USDA's response is attached.

As set forth in the original petition and below, a substantial body of scientific evidence, analyzed by expert organizations such as the World Cancer Research Fund and the American Institute for Cancer Research, attributes the consumption of processed meat to significantly increased cancer risk. Critically, a recent study conducted by the National Institutes of Health (“NIH”) and published after the submission of TCP’s petition, provides new evidence that reducing processed meat intake reduces the mortality associated with cancer and cardiovascular disease.

By continuing to allow the distribution of processed meat products to children, the USDA fails to implement one of the primary goals of the National School Lunch Act, which is to safeguard and improve children’s health. Given the ever-increasing body of evidence gathered by expert organizations and government agencies, TCP submits this amended petition, pursuant to the United States Constitution,¹ the Administrative Procedure Act,² and the USDA’s implementing regulations,³ requesting that the Secretary of the USDA take the following actions necessary to comply with the express intent of the National School Lunch Act and end federal support and encouragement of unhealthy foods in school lunches for children.

II. ACTION REQUESTED

The Cancer Project petitions the Secretary of the United States Department of Agriculture to:

- (1) Institute an examination or investigation into the significant dangers of processed meats⁴ in light of the increasing and plentiful body of accepted scientific evidence concluding that the ingestion of processed meat products causes an increased risk of cancer, especially colorectal cancer.
- (2) Determine whether the USDA may continue to make available unhealthful processed meats for purchase, subsidy, and reimbursement, and comply with the National School Lunch Act, 42 U.S.C. § 1751, which mandates:

[A]s a measure of national security, to safeguard the health and well-being of the Nation’s children and to encourage the domestic consumption of nutritious agricultural commodities and other food, by assisting the States,

¹ U.S. Const. amend I.

² 5 U.S.C. § 553(e).

³ 7 C.F.R. § 1.28.

⁴ “Processed meat” refers to meat preserved by smoking, curing or salting, or addition of chemical preservatives such as nitrites and nitrates, including that contained in processed foods. See World Cancer Research Fund (“WCRF”) and American Institute for Cancer Research (“AICR”) (2007). *Second Report on Food, Nutrition, Physical Activity and the Prevention of Cancer: a Global Perspective* (“WCRF Second Report”) at xix.

through grants-in-aid and other means, in providing an adequate supply of foods and other facilities for the establishment, maintenance, operation, and expansion of nonprofit school lunch programs.

- (3) Discontinue the inclusion of processed meats and poultry on the list of commodities available for purchase from the USDA under the Child Nutrition Commodity Programs, including the National School Lunch Program, in light of the findings sought in (1) and (2).
- (4) Discontinue reimbursement, under the Child Nutrition Commodity Programs, including the National School Lunch Program, to schools for lunches that include processed meats.
- (5) Encourage schools that offer processed meats to offer alternatives to processed meats in their meal plans and at school-hosted functions.
- (6) Promulgate regulations determining processed meat and poultry products to be unhealthful and a leading cause of colorectal cancer and thus unavailable for funding, purchasing, or reimbursement through the Child Nutrition Commodity Programs including the National School Lunch Program.
- (7) Enforce 7 C.F.R. § 210.10 by requiring the FNS nutrition education program to provide information and educational material on the deleterious effects of processed meats on human health to state agencies, schools, parents, and students.
- (8) Discontinue the announcement for and the receipt of bids from suppliers selling to the USDA, for redistribution through the Child Nutrition Commodity Programs, including the National School Lunch Program, processed meat products, including ham, luncheon meat, pork sausage crumbles, pork sausage links, pork sausage patties, pork sloppy joes, and any other processed meat or poultry found to increase the risk of cancer.

III. PARTIES

Petitioner, The Cancer Project, is a national health advocacy nonprofit located at 5100 Wisconsin Ave., NW, Washington, D.C., 20016. TCP is a collaboration of physicians, researchers, and nutritionists joining together to educate the public about the benefits of a healthy diet for cancer prevention and survival. TCP offers free nutrition classes throughout the country, conducts research, and advocates for healthier federal food policies.

IV. ARGUMENT

THE USDA FAILS TO COMPLY WITH THE NATIONAL SCHOOL LUNCH ACT BY PERMITTING COMMODITY MEAT TO BE PROCESSED AND THEN DISTRIBUTED, SUBSIDIZED, AND REIMBURSED THROUGH THE NATIONAL SCHOOL LUNCH PROGRAM

Congress has repeatedly given the USDA the authority to protect both the health and welfare of the nation's children and to protect and cultivate the nation's agricultural sector. In passing the National School Lunch Act, 42 U.S.C. § 1751, *et seq.*, Congress expressly mandated the dual goals of supporting "the health and well-being of the Nation's children" and "encourag[ing] the domestic consumption of nutritious agricultural commodities." However, the USDA compromises the health of the nation's children by ignoring convincing and accepted scientific evidence on the deleterious effects of consumption of processed meat and poultry. Contravening its mandate, the USDA facilitates, permits, and funds the purchase of processed meat and poultry for children in school, thus increasing their risk of cancer.

Processed meat products, including ham, bacon, pastrami, salami, bologna, liverwurst, bratwurst, sausages, frankfurters, hot dogs, luncheon meats, and, depending on the processing, hamburgers and minced meats,⁵ represent a broad category of meat products that are often prepared and/or preserved by curing, smoking, salting, or adding chemical preservatives, such as nitrites and nitrates. On March 23, 2009, scientists from the NIH published a ten-year study of more than a half-million people that investigated the relationship between meat intake and mortality.⁶ The study concluded that higher consumption of processed meat leads to an overall increased risk of mortality, cancer mortality, and cardiovascular disease mortality.⁷ This conclusion also finds support in a review of 58 scientific studies that concluded that consuming processed meat is strongly associated with the specific increased risk of colorectal cancer,⁸ the fourth most common cancer in men and women.⁹

Cancer risk is strongly influenced by environmental exposures; the intestinal tract is in constant contact with foods, food additives, and the products of digestion. This means that individuals who consume processed meats are at a significantly increased risk of developing colorectal cancer, compared with those who avoid consuming processed

⁵ See WCRF and AICR (2007). *WCRF Second Report* at 117; and Ward, M.H. et al. (2007). *Processed meat intake, CYP2A6 activity and risk of colorectal adenoma*. *CARCINOGENESIS* 28(6): 1210-1216, 1210.

⁶ Sinha, R. et al. (2009). *Meat Intake and Mortality: A Prospective Study of Over Half a Million People*. *ARCH. INTERN. MED.* 169(6): 562-571.

⁷ Sinha, R. et al. (2009) at 565.

⁸ In 2007, the World Cancer Research Fund and American Institute for Cancer Research released a report, *Food, Nutrition, Physical Activity and the Prevention of Cancer: a Global Perspective* that concluded that "Processed meat is a convincing cause of colorectal cancer." *WCRF Second Report* at 123.

⁹ The National Cancer Institute estimates predict that, in 2008, 108,070 individuals will develop colon cancer, 40,740 will develop rectal cancer, and 49,960 will die from these conditions. (NCI 2008).

meats. Moreover, the risk increases with increased consumption. For example, the NIH study concluded that those who consumed the lowest amounts of processed meat had the lowest risks for cancer mortality.¹⁰ According to the review conducted by the World Cancer Research Fund and the American Institute for Cancer Research, risk increases on average by 21 percent for every 50 grams of processed meat consumed daily. A 50-gram serving is approximately the size of a typical hot dog. The review also cites evidence that consuming processed meats may also contribute to cancers of the esophagus, lung, stomach, and prostate.¹¹

Thus, in order to protect the health and well-being of the nation's children, the USDA must eliminate the availability of processed meats through the Child Nutrition Commodity Programs, including the National School Lunch Program. By acting on the requests made by TCP, the USDA will both comply with the National School Lunch Act and meet its responsibilities to the nation's children. Moreover, this will be achieved while allowing processed meats to be sold at prices set by the marketplace, not by the federal government.

In determining the nutritious quality of a school lunch, the USDA considers many factors. For example, school lunches must meet the applicable recommendations of the Dietary Guidelines for Americans, which recommend that no more than 30 percent of an individual's calories come from fat and less than 10 percent from saturated fat. Regulations also establish a standard for school lunches to provide one-third of the Recommended Dietary Allowances of protein, vitamin A, vitamin C, iron, calcium, and calories. However, the USDA fails to look at other attributes of food in determining whether it is healthful for inclusion in the school lunch menu. As noted above, the overall healthfulness of food goes beyond the caloric content, fat, and cholesterol. Both the food itself and the cooking process must be examined for overall wholesome qualities, including the risk of cancer and exposure to any other risk of disease or ailment through the National School Lunch Program and Commodity Programs.

V. SCIENTIFIC EVIDENCE SUPPORTING TCP'S PETITION

The link between eating processed meats and cancer has been long studied.¹² To establish consensus on the state of evidence supporting links between specific types of food and cancer risk, the World Cancer Research Fund¹³ and the American Institute for

¹⁰ Sinha, R. et al. (2009) at 564-566.

¹¹ *WCRF Second Report* at 128;

¹² See *WCRF Second Report* at 116; Sinha, R. et al. (2009) at 562-571 (10-year study of more than a half-million people for the relationship among meat intake, including processed meat, and mortality).

¹³ The WCRF global network raises awareness that cancer is largely preventable, funds innovative scientific research and stimulates world wide public health initiatives for the control and prevention of cancer. http://www.wcrf.org/home/about_wcrf_intl.lasso (last accessed on May 28, 2008).

Cancer Research¹⁴ created a panel that, over a five-year period, studied evidence regarding the extent to which cancer can be prevented through healthy patterns of eating and physical activity and created a comprehensive report based on its findings. Previously, the groups had worked together to create and publish *Food, Nutrition and the Prevention of Cancer: a Global Perspective* (1997), which quickly became the standard in the field and helped raise awareness about the importance of research on this issue.¹⁵

The panel's report reviewed all relevant research using the most scientifically valid methodology, provided a comprehensive assessment of the state of evidence linking foods to cancer risk, and provided a set of recommendations on food, nutrition, and physical activity to reduce the risk of cancer.¹⁶ The panel consisted of world-renowned scientists, including world leaders in research of the epidemiology and biology of cancer, nutrition, and public health. To maximize objectivity and transparency of the project, it was separated into three distinct processes: 1) the collection, 2) the analysis, and 3) the recommendations. First, a task force developed a methodology for reviewing the voluminous amounts of scientific literature. Second, research teams collected and reviewed the material based on the developed methodology. And finally, the expert panel assessed and judged the evidence and agreed on recommendations. The report is incorporated herein by reference.

The recent NIH study confirms and extends the findings of the panel's report that consumption of processed meat and cancer are interrelated. Unlike the panel's report, the NIH study evaluated new information to reach its conclusions rather than reviewing existing information. In determining that a cohort of over a half-million people has an increased risk of cancer mortality, the NIH study confirmed the panel's conclusion that processed meat consumption is related to cancer. The study attributed the cancer risk from processed meat to carcinogens like heterocyclic amines, polycyclic aromatic hydrocarbons, iron, and saturated fat.¹⁷ However, the NIH study went one step further than the panel by specifying that higher intake of meat, including processed meats, contributes to cancer mortality. A copy of this study is attached and incorporated herein by reference.

Although the cancer process begins with damage to genes, only a small percentage of cancer is inherited, leaving environmental factors, including food and nutrition, as the most important and modifiable.¹⁸ It has long been estimated that anywhere from 35 to 60 percent of cancer is attributable to diet.¹⁹ "To the extent that environmental factors such as food, nutrition, and physical activity influence the risk of cancer, it is a preventable

¹⁴ American Institute for Cancer Research fosters research on diet and cancer prevention, interprets the evidence, and educates the public about the results.

¹⁵ *WCRF Second Report* at xiv.

¹⁶ *Id.*

¹⁷ Sinha, R. et al. (2009) at 569.

¹⁸ *Id.*

¹⁹ National Cancer Institute. *Cancer Rates and Risks*. Washington, DC:1985, Doll R, Peto R. *The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the United States today*. J Natl Cancer Inst. 1981; 66:1191-308.

disease.”²⁰ Accordingly, the report includes among its recommendations that processed meats be eliminated from people’s diets.²¹

a. Processed Meats and the Risk of Cancer

Processed meats and poultry products contain a variety of potentially carcinogenic chemicals, especially when smoked, cured, preserved, grilled, or cooked at high temperatures. These may include nitrates, nitrites, N-nitroso compounds (“NOCs”) such as N-nitrosodimethylamine (“NDMA”), heme iron, heterocyclic amines (“HCAs”), such as 2-amino-1-methyl-6-phenylimidazo[4,5-b]pyridine (“PhIP”) and 2-amino-3,8-dimethylimidazo[4,5]quinoxaline (“MeIQx”), and polycyclic aromatic hydrocarbons (“PAHs”), such as benzo[α]pyrene (“BAP”).²² The associated cancer risks from these chemical components through the consumption of processed meat products have been described for decades. N-nitrosamines and NOCs were identified as carcinogenic substances over 50 years ago.²³

Nitrites used in meats as a preservative, as well as a coloring and flavoring agent, can combine with amino acid degradation products during the curing process or during digestion to produce N-nitroso compounds (nitrosamines or nitrosamides). Nitrates, used as preservatives, are converted to nitrites. In addition, processed meats cooked at high temperatures may contain chemical carcinogens, including HCAs and PAHs. Moreover, heme iron, plentiful in red and processed meats, promotes the production of N-nitroso compounds, and its iron content leads to free radical production.

Substantial evidence from cohort and case-control studies indicates that processed meat is a convincing cause of colorectal cancer. Meta-analyses find a 21 percent increased risk per 50-gram serving per day.²⁴

b. Chemicals that Increase the Risk of Cancer

i. NOCs

A body of scientific literature concludes that NOCs exhibit mutagenic and carcinogenic activity and are associated with an increased risk of cancer of the esophagus, oral cavity, pharynx, larynx, lung, and colorectum.²⁵ NOCs are formed as a result of the nitrosation of amines, amides, and amino acids by nitrites and nitrates, which are commonly used as

²⁰ *WCRF Second Report* at xiv.

²¹ *Id.* at 382.

²² Jakszyn, P. et al. (2004). *Development of a Food Database of Nitrosamines, Heterocyclic Amines, and Polycyclic Aromatic Hydrocarbons*. J. NUTR. 134: 2011-2014, 2011.

²³ See Bartsch, H. and Montesano, R. (1984). *Relevance of nitrosamines to human cancer*. CARCINOGENESIS 5(11): 1381-1393, 1381.

²⁴ *WCRF Second Report* at 123.

²⁵ See Cross A.J. et al. (2007).

food preservatives in processed meat products.²⁶ Consumption of processed meat, especially processed red meat, has a dose response consistent with the endogenous formation of NOCs, resulting in increased amounts of these compounds in the gastrointestinal tract.²⁷ Thus, due to the endogenous and exogenous exposure from NOCs through the consumption of processed meat products, consumers of these products have an increased risk for gastrointestinal cancers, such as colorectal cancer.²⁸ Additionally, NOC metabolites (metabolically activated NOCs) may contribute to an increased risk of leukemia as well as colon, stomach, esophagus, and brain cancer by inducing the formation of DNA-adducts and miscoding of non-complementary bases during polyribonucleotide and polydeoxyribonucleotide synthesis.²⁹ It is important to note that no safe threshold dose, at which tumor formation would not be expected to occur, has been determined for NOCs. Moreover, NOCs that are carcinogenic in animals are commonly considered human carcinogens for regulatory purposes when establishing safety levels.³⁰

One of the most studied NOCs, NDMA, a nitrosamine present in processed meat products, was listed as a human carcinogen by the State of California in 1987.³¹ Similarly, the International Agency for Research on Cancer (“IARC”), which is part of the World Health Organization, identified NDMA as a probable and possible human carcinogen.³² The U.S. Department of Health and Human Services (“DHHS”) identified NDMA as a substance reasonably anticipated to cause cancer.³³

²⁶ Larsson, S.C., Orsini, N. and Wolk, A. (2006). *Processed Meat Consumption and Stomach Cancer Risk: A Meta-Analysis*. J. NATL CANC. INST. 98(15): 1078-1087, 1085.

²⁷ See Lunn, J., Pollock, J. and Bingham, S. (2004). *The effect of increased red and processed meat on endogenous formation of N-nitroso compounds and DNA strand breaks in ileostomists*. CANCER EPIDEMIOL. BIOMARKERS PREV. 13: A 95-1852.

²⁸ Mirvish, S.S. et al. (2002) at 35268 and See Jakszyn, P. et al. (2006). *Endogenous versus exogenous exposure to N-nitroso compounds and gastric cancer risk in the European Prospective Investigation into Cancer and Nutrition (EPIC-EURGAST) study*. CARCINOGENESIS 27(7): 1497-1501, 1499; Risch, H.A. (2003). *Etiology of Pancreatic Cancer, With a Hypothesis Concerning the Role of N-Nitroso Compounds and Excess Gastric Acidity*. J. NATL. CANCER INST. 95(13): 948-960, 950.

²⁹ Mirvish, S.S. et al. (2002) at 35268; Bartsch, H. and Montesano, R. (1984). *Relevance of nitrosamines to human cancer*. CARCINOGENESIS 5(11): 1381-1393, 1384-1385; also see Bingham, S.A. (2000). *Diet and colorectal cancer prevention*. BIOCHEM. SOCIETY TRANSACTIONS 28(2): 12-16.

³⁰ European Commission, Scientific Committee for Food (1995). *Report of the Scientific Committee for Food*, 38th Series: 1-54, 20 and See Bingham, S.A. et al. (2002). *Effect of white versus red meat on endogenous N-nitrosation in the human colon and further evidence of a dose response*. J. NUTR., 132, 3522S-3525S; Cross, A.J. et al. (2003). *Haem, not protein or inorganic iron, is responsible for endogenous intestinal N-nitrosation arising from red meat*. CANCER RES., 63, 2358-2360.

³¹ See Environmental Protection Agency Office of Environmental Health Hazard Assessment (“OEHH”) (2008). *Chemicals Known to the State to Cause Cancer or Reproductive Toxicity*. http://www.oehha.ca.gov/prop65/prop65_list/files/singlelist032108.xls (last accessed March 21, 2008).

³² See IARC (2007). *Agents Reviewed by the IARC Monographs, Vols. 1-98, 4*. <http://monographs.iarc.fr/ENG/Classification/Listagentsalphorder.pdf> (last accessed March 21, 2008).

³³ See U.S. DHHS, Public Health Service, National Toxicology Program (2005). *Report on Carcinogens, Eleventh Edition*. <http://ntp.niehs.nih.gov/index.cfm?objectid=32BA9724-F1F6-975E-7FCE50709CB4C932> (last accessed March 21, 2008).

ii. HEME

Heme, a red organic pigment, is the iron porphyrin component of hemoproteins, such as hemoglobin and myoglobin.³⁴ Dietary heme forms a highly cytotoxic metabolite that damages the colonic mucosa, resulting in the increased risk of gastric and colon cancer.³⁵ Due to the contribution of heme to NOC formation, the consumption of nitrate and nitrite-rich processed meat products leads to an increased risk for gastrointestinal cancers, such as colorectal cancer. Heme iron, as opposed to inorganic iron, is considered to be a principal determinant of endogenous gastrointestinal N-nitrosation by acting as a nitrosating agent, and, for reasons similar to those applied to NOCs, cannot have a determined safe threshold level.³⁶

iii. HCAs

HCAs have been considered major contributors to mutagenicity of cooked meat products. Therefore, consuming these products poses a public health risk. Through metabolic pathways such as cytochrome-mediated (e.g., CYP1 and CYP2) N-hydroxylation and O-esterification by phase II enzymes, HCA compounds create genotoxic metabolites that are known mutagens and carcinogens.³⁷ HCAs form inside and on the surface of meats from creatine or creatinine, amino acids, and sugars as a result of exposure to high temperatures through cooking processes, including barbecuing, frying, roasting, and grilling.³⁸

HCAs detected in cooked processed meat products that are suspected of increasing cancer risk include 2-amino-3-methylimidazo[4,5-f]quinoline.³⁹ The HCAs 2-amino-3,4,8-trimethylimidazo[4,5]quinoxaline, MeIQx, and PhIP are specifically linked to an increased risk for colorectal cancer.⁴⁰ The State of California has identified PhIP and MeIQx as known human carcinogens since 1994,⁴¹ and the IARC labeled them as possible human carcinogens in 1993.⁴² Because there are no known safe levels of

³⁴ Balder, H.F. et al. (2006). *Heme and Chlorophyll Intake and Risk of Colorectal Cancer in the Netherlands Cohort Study*. *CANCER EPIDEMIOLOGY AND BIOMARKERS* 15(4): 717-725, 717.

³⁵ See Balder, H.F. et al. (2006) at 717; Lunn, J.C. et al. (2004) at 689.

³⁶ See Ward, M.H. et al. (2007) at 1215; Cross, A.J. et al. (2007); Jakszyn, P. et al. (2006) at 1497.

³⁷ See Gooderham, N.J. et al. (2001-a). *Food-Derived Heterocyclic Amine Mutagens: Variable Metabolism and Significance to Humans*. *DRUG METABOLISM AND DISPOSITION* 29(4): 529-534, 529.

³⁸ Kikugawa, K. (2004). *Prevention of mutagen formation in heated meats and model systems*. *MUTAGENESIS* 19(6): 431-439, 431.

³⁹ See IARC. *Some Naturally Occurring Substances: Food Items and Constituents, Heterocyclic Aromatic Amines and Mycotoxins*, Vol. 56 at 11. <http://monographs.iarc.fr/ENG/Monographs/vol56/volume56.pdf> (last accessed March 20, 2008).

⁴⁰ See Sinha, R. et al. (2005). *Meat, Meat Cooking Methods and Preservation, and Risk for Colorectal Adenoma*. *CANCER RES.* 65(17): 8034-8042.

⁴¹ OEHHA (2008). *Chemicals Known to the State to Cause Cancer or Reproductive Toxicity*. http://www.oehha.ca.gov/prop65/prop65_list/files/singlelist032108.xls (last accessed March 21, 2008).

⁴² IARC (2007). *Agents Reviewed by the IARC Monographs, Vols. 1-98*, 4. <http://monographs.iarc.fr/ENG/Classification/Listagentsalphorder.pdf> (last accessed March 21, 2008).

exposure, PhIP, MeIQx, and any other likely genotoxic compounds should be avoided as much as possible.⁴³

iv. PAHs

Studied for decades, PAHs have also been found to contribute to mutagenic and carcinogenic activity. Processed meat products contain precursors to PAHs, creating PAHs when animal fat drips onto a heated surface and burns.⁴⁴ Processed meat products are thereby of concern due to the routine use of high temperature cooking methods to prepare such foods.⁴⁵ Through a process of metabolic activation by cytochrome P450 enzymes and/or peroxidases, PAHs become reactive intermediates with carcinogenic potential.⁴⁶ PAH exposure results in genotoxic markers such as DNA adducts, chromosome aberrations, sister chromatid exchanges, *ras* oncogene over expression, and impacts on cellular pathways.⁴⁷ PAHs generally exist in complex mixtures, making it difficult to pinpoint the relative contribution of any individual PAH to carcinogenic effects.

However, one of the most prevalent and readily identifiable carcinogenic PAHs is BAP.⁴⁸ Since the 1930s, BAP has been studied for its carcinogenic effect.⁴⁹ BAP was listed as a known carcinogen by the State of California in 1987 and was upgraded to this status by the IARC in 2007.⁵⁰ The DHHS has identified BAP and PAHs as substances reasonably

⁴³ Food Standards Australia New Zealand (2005). *Scientific Assessment of the Public Health and Safety of Poultry Meat in Australia*. 1-228, 172;

http://www.foodstandards.gov.au/_srcfiles/P282_Poultry%20_%20DAR%20Attach3.doc (last accessed March 24, 2008). Gooderham, N.J. et al. (1996). *Heterocyclic amines: evaluation of their role in diet associated with human cancer*. BR. J. CLIN. PHARMACOL. 42: 91-98, 91.

⁴⁴ Sinha, R. et al. (2005). *Dietary Benzo[a]Pyrene Intake and Risk of Colorectal Adenoma*. CANCER EPIDEMIOL. BIOMARKERS PREV. 14(8): 2030-2034, 2030.

⁴⁵ See IARC: Polycyclic Aromatic Hydrocarbons, § 5.4, August 2006.

<http://monographs.iarc.fr/ENG/Meetings/92-pahs.pdf> (last accessed March 20, 2008).

⁴⁶ Melendez-Colon, V.J., Luch, A., Seidel, A. and Barid, W.M. (1999). *Cancer initiation by polycyclic aromatic hydrocarbons results from formation of stable DNA adducts rather than apurinic sites*. CARCINOGENESIS 20(10): 1885-1891, 1885.

⁴⁷ Ding et al. (2006). *Effects of Polycyclic Aromatic Hydrocarbons (PAHs) on Vascular Endothelial Growth Factor Induction through Phosphatidylinositol 3-Kinase/AP-1-dependent HIF-1 α -Independent Pathway*. J. BIOL. CHEM. 281(14): 9093-9100, 9099.

⁴⁸ See IARC (2007). *Overall Evaluations of Carcinogenicity to Humans*.

<http://monographs.iarc.fr/ENG/Classification/crthgr01.php> (last accessed March 20, 2008).

⁴⁹ Rubin, H. (2001). *Synergistic mechanisms in carcinogenesis by polycyclic aromatic hydrocarbons and by tobacco smoke: a biohistorical perspective with updates*. CARCINOGENESIS 22(12): 1903-1930, 1903.

⁵⁰ IARC (2007). *Agents Reviewed by the IARC Monographs, Vols. 1-98, 4*.

<http://monographs.iarc.fr/ENG/Classification/Listagentsalphorder.pdf> (last accessed March 21, 2008);

OEHHA (2008). *Chemicals Known to the State to Cause Cancer or Reproductive Toxicity*.

http://www.oehha.ca.gov/prop65/prop65_list/files/singlelist032108.xls (last accessed March 21, 2008).

anticipated to cause cancer.⁵¹ Because there is no known safe level of exposure for BAP or other genotoxic PAHs, they should be avoided as much as possible.⁵²

c. Processed Meats and the Risk of Cardiovascular Disease

The recent NIH study of more than a half-million people concluded that the group that consumed the highest amount of processed meat was subject to an increased risk of death from cardiovascular disease.⁵³ The study based this conclusion, in part, on the consequential elevated blood pressure that is positively associated with higher consumption of processed meat.⁵⁴ By reducing the total consumption of processed meat from 22.6 grams per 1000 calories to 1.6 grams per 1000 calories, cardiovascular disease mortality could be reduced by 20% in women.⁵⁵ Thus, the NIH study supports reducing processed meat consumption to reduce the risk of cardiovascular disease mortality.

⁵¹ U.S. DHHS, Public Health Service, National Toxicology Program (2005). *Report on Carcinogens, Eleventh Edition*. <http://ntp.niehs.nih.gov/index.cfm?objectid=32BA9724-F1F6-975E-7FCE50709CB4C932> (last accessed March 21, 2008).

⁵² *Id.* at 169.

⁵³ Sinha, R. et al. (2009) at 565.

⁵⁴ Sinha, R. et al. (2009) at 569.

⁵⁵ Sinha, R. et al. (2009) at 567.

VI. CONCLUSION

In light of the evidence presented in this petition, and in order for the agency to comply with its own statutory and regulatory requirements, TCP requests that the USDA enact the suggested rulemaking and amendments to particular rules to bring the USDA's programs into compliance with the National School Lunch Act. As required by 7 C.F.R. § 1.28, the USDA must give this petition prompt consideration. Therefore, TCP requests a substantive response to this petition within one hundred eighty (180) calendar days.⁵⁶

Respectfully submitted,



Neal D. Barnard, M.D
President
The Cancer Project
5100 Wisconsin Ave., NW, Suite 400
Washington, D.C. 20016
(202) 686-2210



Daniel Kinburn
General Counsel
The Cancer Project
5100 Wisconsin Ave., N.W., Suite 400
Washington, D.C. 20016
(202) 686-2210

⁵⁶ See 42 U.S.C. § 7604(a) requiring notice of 180 days prior to commencing an action for unreasonable delay.

Exhibit D



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

OCT - 7 2009

Neal D. Barnard, M.D.
President
The Cancer Project
5100 Wisconsin Avenue, NW, Suite 400
Washington, DC 20016

Daniel Kinburn
General Counsel
The Cancer Project
5100 Wisconsin Avenue, NW, Suite 400
Washington, DC 20016

Re: Petition to the United States Department of Agriculture Regarding Processed Meats

Dear Dr. Barnard and Mr. Kinburn:

This letter responds to your petition dated June 16, 2009, in which you asked Thomas J. Vilsack, the Secretary of Agriculture, to remove processed meats from the school lunch program. In support of your request, you cite the work done largely by the World Cancer Research Fund (WCRF) and the American Institute for Cancer Research (AICR). You also include three similar written statements from three cancer experts, who all cite the work done by WCRF and AICR and express their personal views that it would be in the interest of the public health if the government stopped subsidizing and promoting processed meats through the school lunch program.

After considering your petition, the Department of Agriculture (USDA) has decided to deny it without prejudice.

In the short time that the Obama Administration has been in office, it has made a significant commitment to find ways to prevent and find a cure for cancer. The President's Fiscal Year 2010 budget proposes to invest over \$6.6 billion for cancer research across the National Institutes of Health. The goal is to invest resources in ways that will have the greatest possible impact on developing innovative diagnostics, treatments, and cures for cancer. The President also signed the Family Smoking Prevention and Tobacco Control Act to reduce the leading preventable cause of cancer. Moreover, the American Recovery and Reinvestment Act launched a significant effort to find a cure for cancer. Under this legislation, the National Cancer Institute is distributing

funds for three significant initiatives: efforts to expand the cancer genome atlas, to design and develop a personalized cancer care drug development program, and to create a network of centers to converge the physical sciences with cancer biology.

With this strong Administration commitment to fighting cancer as background, we have reviewed your petition.

We read your petition with great interest. You have cited statements from respected scientists. The fact is, however, that USDA does not possess the expertise to assess the strength of the evidence that you present, nor is USDA the department in the U.S. Government charged with doing so. For USDA to obtain the type of review needed to assess your petition, the Department would, quite frankly, have to use a significant amount of its resources in ways that Congress has not authorized them to be used, to obtain the review from other agencies of the U.S. Government.

USDA is unwilling to take such a step at this time because your petition fails to provide the factual predicate that would be necessary to justify use of USDA resources to obtain such review. While you cite three experts expressing their individual views, you do not cite any consensus documents of the U.S. Government or of the leading world bodies with cancer expertise in support of the action you urge. You cite a recent study published in the *Archives of Internal Medicine*, but the cohort evaluated was composed of people aged 50 to 71, and revealed modest associations with morbidity and mortality in this specific age group. Your petition focuses on school lunch.

Given the state of the record, there is no alternative but to deny your petition without prejudice. Should expert consensus develop that would support the action on processed meats that you seek, you are of course free to re-urge this action to this Department. We would expect, however, that to justify the action, such consensus would need to include the institutional consensus (not simply an article published in an agency journal) of appropriate U.S. Government agencies with cancer expertise such as the National Cancer Institute, the President's Cancer Panel, the Surgeon General, and the Centers for Disease Control and Prevention, and leading national and international bodies with recognized expertise on cancer.

Therefore, your petition is hereby denied without prejudice.

Sincerely,



Philip S. Derfler
Assistant Administrator
Office of Policy and Program Development